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Trans-gender
Reassignment Surgery

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EXECUTIVE SUMMARY

Aim

There is no public funding for gender reassignment surgery (GRS) in the public health system within New Zealand. Patients either self-fund or apply for funding from the nationally managed special high cost treatment pool (SHCTP). The current position of the Ministry of Health is that GRS does not meet criteria for the provision of funding through SHCTP. The Ministry of Health has requested this review with the aim of determining the level of evidence supporting the effectiveness of GRS in a subgroup of patients. This will better inform guidelines for the further consideration of applications under the SHCTP exceptional circumstances criterion.

Population, intervention, comparator, outcomes

The population of interest is people with a diagnosis of transsexualism based on the ICD and DSM criteria and the Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders. The intervention of interest is sex reassignment surgery in transsexual people (both M to F and F to M) having genital reconstruction surgery and any other additional procedures. The comparator of interest is the same or other primary transsexual groups (pre-operative, post-operative) or secondary transsexual groups. Few studies have study designs with control groups. Outcomes measuring effectiveness based on reduced consumption of psychiatric services, mortality from suicide, increased satisfaction, improved quality of life, change in employment status and financial situation will be considered.

Literature search

The MeSH heading Transsexualism was used and additional keywords included gender reassignment, sex reassignment, gender dysphoria, gender identity disorder, transsexual, trans-sexual, transgender, trans-gender. The NZHTA Core Search protocol was employed and included major bibliographic databases (Medline, Embase etc) and review databases (EBM reviews, Cochrane, DARE etc). Articles available at December 2001 in English published since 1980 were considered.

Results

Some 593 possibly relevant articles in abstract form were identified of which 70 articles were retrieved in full text. Ten studies were selected for appraisal after the application of the inclusion and exclusion criteria. The study designs of the included studies comprised one systematic review, one prospective controlled study, one retrospective cohort study and seven quasi-experimental studies.

Conclusion

There is insufficient evidence to support the efficacy of gender reassignment surgery for specific subgroups of persons selected for surgical intervention. Subgroups of transsexual people who will most likely benefit from sex reassignment surgery are not identifiable from the evidence reviewed. The quality of the evidence is poor and based on a small number of studies with weak study designs and significant methodological limitations.

The reviewed studies may indicate that early, rather than delayed, sex reassignment surgery is of greater benefit to transsexual people who have gone through rigorous assessment procedures and have been accepted for surgery. Also, the reviewed studies identify characteristics of groups defined as core and non-core transsexual people, but these characteristics are heterogeneous and anecdotal.

Gender reassignment surgery may benefit some carefully assessed and selected transsexual people who have satisfied recognised diagnostic and eligibility criteria, and have received recognised standards of care for surgery. More research is required to improve the evidence base identifying the subgroups of transsexual people most likely to benefit from sex reassignment surgery.

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LIST OF ABBREVIATIONS

DSM-III/IV	–	Diagnostic and statistical manual of mental disorders 3 rd /4 th edition
F	–	Female
FM	–	Female to Male transsexual
grp	–	group
GRS	–	Gender Reassignment Surgery
ICD-10	–	International Classification of Diseases 10 th edition
N	–	Number
M	–	Male
MF	–	Male to Female transsexual
RCT	–	Randomised Controlled Trial
S.D.	–	Standard Deviation
SHCTP	–	Special High Cost Treatment Pool
HP	–	Hesitating patient
SR	–	Sex reassignment
UWS	–	Unchanged wish for surgery
SU	–	Surgical
IG	–	Initial gender
TV	–	Transvestite
PRET	–	Pre-operative transsexual
POT	–	Post-operative transsexual

Background

There is no tagged funding for gender reassignment surgery (GRS) in the public health system within New Zealand. Therefore, surgery is either performed in the private sector or overseas with the person self-funding, or applying for funding from the nationally managed special high cost treatment pool (SHCTP).

The current position of the Ministry of Health is that GRS does not meet two of the criteria for the provision of funding through SHCTP. Specifically, (i) the treatment has proven efficacy through appropriate clinical trials, and preferably has also been established as effective when applied in regular practice, and (ii) treatment would lead to reasonable prospects of survival and to an improved quality of life after treatment. Criterion (i) is not met, and criterion (ii) has not been established.

Therefore, all applications for GRS to be funded from the SHCTP have been declined. Where applications fail to meet all the SHCTP funding criteria, a further examination of the circumstances of the case is undertaken to determine whether the circumstances are so exceptional that it would be appropriate to fund the application even where the criteria are not met.

There have been 11 applications for male to female GRS to the SHCTP between 1 July, 1999 and 31, July 2001. This surgery can be performed within New Zealand. To date there have not been any applications for female to male GRS and this surgery is not available within New Zealand.

The Ministry of Health has requested this review on the basis of determining whether there is any evidence to support the effectiveness of GRS in a subgroup of patients, and to inform the development of guidelines by an expert panel to assist in the further consideration of applications under the exceptional circumstances criterion described above.

Tech brief request

This tech brief was requested by Sara Fredericks, Case Manager, Health Services Policy, Personal and Family Health Directorate, Ministry of Health, New Zealand Government.

Tech Brief topic

Research questions

1. Are there particular subgroups of people with transsexualism who have met eligibility criteria for gender reassignment surgery (GRS) where evidence of effectiveness of that surgery exists?
2. If there is evidence of effectiveness, what subgroups would benefit from GRS?

POPULATION

The population of interest is people with a diagnosis of transsexualism based on the ICD and DSM criteria in place at the time the study was conducted. Eligibility criteria for GRS will be based on the criteria set out in Harry Benjamin International Gender Dysphoria Association's Standards of Care for Gender Identity Disorders version in place at the time the study was conducted (2001). Although these are now generally recognised standards and are met in routine practice other diagnostic and eligibility criteria are also used in clinical practice and are found in the literature. The differential diagnosis of gender dysphoria is broad and there is controversy over diagnosis and treatment (Roberto, 1983; Brown, 1990).

Nomenclature has evolved around the use of the term transsexualism and gender identity disorder. The DSM-III recognises the diagnosis of transsexualism. It was defined as gender dysphoric individuals who demonstrated at least two years of continuous interest in transforming the sex of their bodies and their social gender status. However, the term transsexualism has been replaced by gender identity disorder in DSM-IV. Depending on their age, those with a strong and persistent cross-gender identification and a persistent discomfort with their sex or a sense of inappropriateness in the gender role of that sex, were to be diagnosed as Gender Identity Disorder of Childhood, Adolescence, or Adulthood. For persons who did not meet these criteria, Gender Identity Disorder Not Otherwise Specified was to be used.

The ICD-10 provides five diagnoses for the gender identity disorders including Transsexualism, Dual-role Transvestism, Gender Identity Disorder of Childhood (separately defined for girls and boys), Other Gender Identity Disorders and Gender Identity Disorder, Unspecified.

Transsexualism has three criteria under the ICD-10 definition:

1. the desire to live and be accepted as a member of the opposite sex, usually accompanied by the wish to make his or her body as congruent as possible with the preferred sex through surgery and hormone treatment
2. the transsexual identity has been present persistently for at least two years
3. the disorder is not a symptom of another mental disorder or a chromosomal abnormality.

In primary transsexualism, the transsexual impulse stems from childhood and is persistent throughout life. In secondary transsexualism, it tends to appear later and the patient may go through phases of transvestism or effeminate homosexuality before converting to transsexualism.

INTERVENTION

The therapeutic approach to gender identity disorder consists of three parts: a real life experience in the desired role, hormones of the desired gender, and surgery to change the genitalia and other sex characteristics. The most typical order, if all three elements are undertaken, is hormones followed by real life experience and, finally, surgery.

For M to F transsexuals selected for surgery, procedures may include genital reconstruction (vaginoplasty, penectomy, orchidectomy, clitoroplasty), breast augmentation and cosmetic surgery

(facial reshaping, rhinoplasty, abdominoplasty, laryngeal shaving, vocal cord shortening, hair transplants). For F to M transsexuals, surgical procedures may include genital reconstruction (phalloplasty, genitoplasty, hysterectomy, bilateral oophorectomy) mastectomy, chest wall contouring and cosmetic surgery (Lothstein & Brown, 1992).

The intervention of interest is sex reassignment surgery for both M to F and F to M transsexuals having genital reconstruction surgery and any other additional procedures.

COMPARATOR

The comparator of interest ideally would be healthy biological male and female controls but in the literature few studies have study designs with control groups. Comparison groups are most often pre- and post-operative transsexuals, groups of transsexuals at different stages in the GRS process or with differential diagnoses, pre- and post-test on the same transsexual group or a single arm follow-up study with no comparison group.

OUTCOMES

Evidence of effectiveness will be based on:

- reduced consumption of psychiatric services
- reduced mortality from suicide
- increased satisfaction and improved quality of life. An aspect of patient satisfaction is also post-operative regret and request for surgery reversal
- alteration in employment status and financial situation.

Methods

LEVEL OF EVIDENCE CONSIDERED IN TECH BRIEFS

Tech Briefs are rapidly produced assessments of the best available evidence for a topic of highly limited scope. They are less rigorous than systematic reviews. Best evidence is indicated by research designs which are least susceptible to bias according to the National Health and Medical Research Council's (NHMRC) criteria (see **Appendix 1**). Where methodologically acceptable and applicable, appraised evidence is limited to systematic reviews, meta-analyses, evidence-based clinical practice guidelines, health technology assessments and randomised controlled trials (RCTs). There was little material of this level of evidence available for the Trans-gender Reassignment Surgery Tech Brief, so poorer quality evidence from cohort, case-control and quasi-experimental studies have also been included.

MAIN SEARCH TERMS

Details of the search strategy are presented in **Appendix 2**.

MeSH heading: Transsexualism

Additional keywords: gender reassignment, sex reassignment, gender dysphoria, gender identity disorder, transsexual, trans-sexual, transgender, trans-gender

SEARCH SOURCES

The NZHTA Core Search was employed. Characteristics of the Core search include: essential sources only, major databases and secondary sources, and mostly published and indexed literature. For more detail about the search sources refer to the NZHTA Search Protocol at <http://nzhta.chmeds.ac.nz/nzhtainfo/protocol.htm> Steps 1-9 (Core sections).

Bibliographic databases

- Medline
- Embase
- Healthstar
- Cinahl
- Psychinfo
- Current Contents
- Science/Social Science Citation Index
- Cochrane Library Controlled Trials Register

Review databases

- Evidence-based medicine reviews
- Cochrane Library
- DARE
- NHS Economic Evaluation Database
- Health Technology Assessment Database

Articles published in English language only were considered.

The search was restricted to literature published since 1980. The search includes information available at December 2001.

STUDY INCLUSION AND EXCLUSION CRITERIA

Inclusion criteria

- evaluation of the outcome of either male to female surgery or female to male surgery
- outcomes considered include:
 - utilisation of psychiatric services
 - mortality from suicide
 - request for operation reversal
 - patient satisfaction and quality of life indicators
 - alteration in employment status
- study written in English and published in 1980 or later.

Exclusion criteria

- study group consists of people with no evidence of gender identity disorder
 - study participants under 16 years of age
 - study primarily considers surgical techniques
 - study in form of abstract only, letter or case presentation
 - narrative reviews
 - followed-up study sample of 20 subjects or less
 - study has no statistical assessment of precision (confidence intervals or *p*-values)
 - study contains inadequately described methods, results or no relevant outcomes
 - study population is overlapping sample from another study.
-

Results

From the above search strategy we identified 593 potentially relevant articles in abstract form of which 70 articles were retrieved in full text (see **Appendix 2** for full strategy search strings). Through the application of the above inclusion and exclusion criteria, 10 studies were selected for appraisal. These comprised one systematic review, one prospective controlled study, one retrospective cohort study and seven quasi-experimental studies with post-test only and before/after designs. Retrieved articles which were excluded are listed in **Appendix 4**. Of the 60 retrieved articles which were excluded from appraisal 14 were narrative reviews, nine were already included in the appraised systematic review and these, along with most of the remainder, had less than 20 sample subjects or inadequate methodology. Included appraised studies are listed in **Appendix 3**, and are described in the Evidence Table below. These detail the study source, design, evidence grading, sample description, outcome measures, results and NZHTA reviewer comments on the study and its validity.

Table 1. Evidence table of appraised articles

Study Source, design and evidence grading	Subject sample description	Outcome measures	Results			Comments
(Best and Stein 1998) Systematic Review United Kingdom Grade III-3	M to F (MF) clients only or where separately identifiable in MF/FM study population. N=559 in 12 studies Exclusion Studies with individual case reports, narrative reviews.	Psychometric measures of well-being, surgical outcomes of GRS.	<ul style="list-style-type: none"> small numbers of male to female transsexual people experience benefit from surgical gender reassignment potential harms great overall quality of evidence poor, methodological limitations in many papers including data not collected prospectively, high losses to follow-up and small case series, lack of validated outcome measures more research in the form of high quality controlled trials are needed to determine long-term benefits and risks the value of Harry Benjamin guidelines dysphoria association guidelines in identifying minimum care standards for surgery applicants acknowledged. 			<ul style="list-style-type: none"> one prospective controlled, one cross-sectional study identified along with numerous case series studies methods poorly described, study inclusion/exclusion criteria, population of interest and outcomes not well defined, variable search source date parameters to April 1998 diverse range of lower level evidence study types combined study quality assessment systematic and well reported.
(Mate-Kole et al. 1990) Prospective controlled study United Kingdom Grade III-2	Pre-operative male transsexuals approved for surgery. Group 1: offered early surgery N=20 Group 2: offered routine surgery N=20 and still on waiting list at evaluation two years later. Group 1 patients were treated with a single stage genital surgery operation.	Assessment of social, sexual activity and personal history, personality and psychoneurotic symptoms.	Outcomes (N range) Changes in social activity over 2 year period (sport, social visits, dancing, eating out) More active Same Less active P-value (Work record N) More active Same Less active P-value	Early surgery: post-operative 15-16 2-4 2 P<0.01 0 19 1 NS	Routine surgery: still on waiting list 1-3 14-16 3-4 NS 0 14 6 P<0.05	<ul style="list-style-type: none"> this study is critically appraised in the systematic review by (Best and Stein 1998) which addressed the efficacy of gender reassignment surgery but not for specific patient groups patient group efficacy outcomes are reported here waiting list group experienced negative changes in test scores over 2 year period for neurotic symptoms, operated group had positive changes in test scores, all significantly different ($p<0.05$) from waiting list group.

Table 1. Evidence table of appraised articles (continued)

Study source, design and evidence grading	Subject sample description	Outcome measures	Results				Comments
(Tsoi 1993) Post-test quasi-experimental Singapore Grade IV	Post-operative Transsexuals 45 MF 36 FM	Assessment including semi-structured questionnaire of quality of life indicators.	Outcomes Good/satisfactory adjustment in (%) Sex organ functioning Pre-operative variables and outcomes (male transsexuals) Age at onset (mean years and S.D.): Petting Cross-dressing	Male Transsexual 91% Good Outcome 16.4 (4.2) 17.9 (3.3)	Female Transsexual 39% Satisfactory outcome 14.0 (2.5) 15.5 (4.7)	P-value P<0.001 P<0.05 P<0.10	<ul style="list-style-type: none"> ▪ this study is critically appraised in the systematic review by (Best and Stein 1998) which addressed the efficacy of gender reassignment surgery but not for specific patient groups ▪ prognostic predictors of outcomes related to patient groups are reported here ▪ work/finance, partner relationship/sexual activity and sex status satisfaction no significant difference between post-op male and female transsexuals ▪ other variables including age at onset, infatuation, first partner were all non-significant predictors. for females none of these pre-op variables could predict differences in outcome.
(Landen et al. 1998) Retrospective cohort Sweden Grade III-3	Applicants for gender reassignment surgery (GRS) (MF/FM) from pre-1972 –1996 Applied for and received surgery or surgery reversal N=218 (13 in GRS regret group; 205 in non-GRS regret group)	Prognostic factors in sex reassignment derived from medical records. Demographic data Education Employment Medical history Diagnosis-gender identity disorder.	Outcomes Predictor (Logistic regression β /se) Poor family support Non-core transsexual group conditions bordering on transvestism and homosexuality rather than extreme transsexualism as differential diagnosis from DSM concept.	GRS regret group c.f. non-regret group $\beta=2.4$ (1.08) $\beta=1.4$ (0.70)		P-value P= 0.026 P=0.046	<ul style="list-style-type: none"> ▪ the GRS regret group comprised 3.8% of retrospective cohort ▪ applicants for GRS in population comprise range of core and non-core transsexual diagnoses ▪ high variability in follow-up since GRS (4-24 years) ▪ prognostic factors of interest not well defined nor medical record coding/quantification from method validation ▪ small numbers in GRS regret group likely insufficient statistical power.

Table 1. Evidence table of appraised articles (continued)

Study source, design and evidence grading	Subject sample description	Outcome measures	Results				Comments
(Smith et al. 2001) Before/after quasi-experimental Netherlands Grade IV	Adolescent having GRS within 1 year of latest treatment (T group: 7 MF and 13 FM) Adolescents not approved for GRS due to rejection, withdrawal of request (NT group: 13 MF and 8 FM)	Psychometric testing for psychological functioning, post-treatment evaluation, body satisfaction, gender dysphoria.	Outcomes (mean score / sd) Gender dysphoria T NT Body dissatisfaction primary sex features T NT Psychological functioning (depression) T NT	Pretest 56.3 (4.6) 46.7(13.9) 17.9 (3.0) 16.1 (5.1) 28.3 (9.8) 31.8 (15.6)	Posttest 13.8 (2.3) 31.1 (14.9) 10.2 (5.7) 13.4(4.9) 21.6 (3.7) 35.2 (14.7)	P-value P<0.001 P=0.002 P<0.001 P=0.04 P=0.01 P=0.63	<ul style="list-style-type: none"> ▪ mean age of pre-test T group 16.6 (range 15-19), NT group 17.3 years (range 13-20), post-test T group 21.0 years (range 19-23), NT group 21.6 years (range 15.7-26.2) ▪ likely selection bias in small adolescent sample, not generalisable to other transsexual age groups ▪ only short-term follow-up of 1 year. only 66% (n=14) of NT group participated in follow-up ▪ outcome measures documented, some validation of questionnaires and test scales ▪ almost all psychological function test scores were not significantly different between groups.
(Blanchard et al. 1989) Post-test quasi-experimental Canada Grade IV	Post-operative transsexuals (MF/FM) with homo/heterosexual orientation (N=111) Vaginoplasty for males and mastectomy for females Homosexual (as biological females, then FM) N=61 Homosexual (as biological males, then MF) N=36 Heterosexual (as biological males, then MF) N=14	Post-operative regret, demographic information on age, education, employment from self-administered questionnaire.	Outcomes (N) Bio F (homosexual) Bio M (homosexual) Bio M (heterosexual) Post-op regret correlation with heterosexual preference	Post-op regret (N) 0/61 0/36 4/14 (29%) r=0.51		P-value P<0.001	<ul style="list-style-type: none"> ▪ age at surgery/follow-up: homosexual F, FM 28.5/37.8; homosexual M, MF 29/34; heterosexual M, MF 41.4/44.6 ▪ many subjects included from previous study and small numbers included in heterosexual M group, low study power and possible selection bias ▪ sexual orientation classification not applied to all patients, 17% relied on clinical charts. Not all assessment tools validated, outcome assessment not blinded ▪ mean time to post-op follow-up 4.4 years (1-13.6 years), Heterosexual GRS regret group 2.9 years. Of original 132 patients, 84.1% followed up ▪ non-significant correlations of regret with patient education, age at surgery or follow-up, biological sex accounting for preference.

Table 1. Evidence table of appraised articles (*continued*)

Study source, design and evidence grading	Subject sample description	Outcome measures	Results				Comments
(Barrett 1998) Before/after quasi-experimental United kingdom Grade IV	Pre-operative (FM) transsexuals (N=23) accepted for phalloplasty Post-operative (FM) transsexuals (N=40) who had undergone phalloplasty	General health, psychological symptoms, social role performance, sex role, employment, income, genital appearance, function relationships from questionnaires and psychometric testing.	Outcomes (mean score) Sex role (post-op group tended towards being androgynous, pre-op a more masculine score) . Genital appearance Statistically significant difference between groups.	Pre-op group 41.7 1.35	Post-op group 51.0 3.85	95% CI 2.5, 16* 1.9, 3.1*	<ul style="list-style-type: none"> ▪ mean age in pre-op group 35 years (range 17-51 years), post-op group mean age 40 (range 24-72 years) ▪ the mean time since phalloplasty in post-op group 46 months (range 1-195 months). Wide variation in follow-up times post-surgery. Only 75% of post-op group followed up, unknown if this group different to those lost to follow-up ▪ small numbers included in study, low study power ▪ some assessment tools and outcome measures not validated ▪ general health, psychological symptoms, social role performance income, employment, sexual function and current relationship all showed no significant difference between the two groups ▪ outcome assessment not blinded.
(Kockott and Fahrner 1987) Post-test quasi-experimental Germany Grade IV	Of N=80 patients, 59 interviewed Transsexuals having SR surgery (N=32) Surgical (SU): 18 MF and 14 FM Transsexuals who had not had SR (N=26) Hesitating (HP): 6 MF, 1 FM Unchanged wish for SR (UWS): 9 MF, 3 FM Not wanting SR at assessment, living as initial gender (IG): 4 MF, 3 FM	Demographic, socioeconomic, contentment with aspired gender, gender role adaptation, psychological adjustment from questionnaire/interview and psychometric testing.	Outcomes (% patients) Financial sufficiency Heterosexual/former partners Cross-gender identity Sexual satisfaction Psychological adjustment (difficulty) follow-up/baseline. No employment Financial sufficiency Content with aspired gender Gender role adaption Sexual satisfaction Significant difference at 5% level.	UWS grp 50% 0% 100% N.S. 33% 50% 50% 42% 45%	HP grp 100% 100% 43% 17% N.S	IG grp 86% N.S	SU grp P<0.05 6% 93% 97% 94% 87% <ul style="list-style-type: none"> ▪ mean age (SU) grp 35.5, (UWS) grp 31.7, (IG) grp 31.8, (HP) grp 40.3. HP grp older, more often married and having children than other groups of 80 patients, 59 (74%) in follow-up assessment. Unknown if this group different to those lost to follow-up. average follow-up 5.5 years since first consultation ▪ small numbers included in study, low study power ▪ some assessment tools and outcome measures not validated ▪ no investigator involvement with interviews in most cases ▪ not all results between groups reported.

Summary and conclusions

SUMMARY

The study designs of the included studies comprised one systematic review, one prospective controlled study, one retrospective cohort study and seven quasi-experimental studies. The systematic review by Best and Stein (1998), concluded that small numbers of transsexual people (M to F transsexuals) may benefit from surgical gender reassignment. The characteristics of particular subgroups of these people were not specifically reported. Although the study appraisal was systematic and thorough, the quality of literature reviewed was poor and the review methods not well described.

Two of the studies appraised in the systematic review (Mate-Kole et al. 1990; Tsoi, 1993) were included but not appraised, as these identified sub-groups of M to F transsexuals experiencing benefit from sex reassignment surgery. The prospective controlled study by Mate-Kole et al. (1990) showed improved social activity, work record and less neurotic symptoms for M to F transsexuals approved for surgery who had early rather than routine surgery. The follow-up study by Tsoi (1993) showed that M to F transsexuals experienced better sexual functioning than F to M transsexuals and some pre-operative age at onset characteristics were predictors of good outcomes in M to F transsexuals.

Three of the appraised studies gave an indication that transsexuals (with stringent and long-term assessment procedures) having early or normal surgery, as opposed to delayed or routine surgery, have better outcomes. The previous study by Mate-Kole et al. (1990) where M to F transsexuals who had early rather than routine surgery had better outcomes. The study by Kockott and Fahrner (1987) identified transsexuals (both M to F and F to M) having had surgery who had improved quality of life compared with those still awaiting surgery, particularly those still hesitating. Finally, the study by Smith et al. (2001) showed that adolescent transsexuals (both M to F and F to M) post-operatively resolved their gender dysphoria, body dissatisfaction and psychological functioning better than those (now older) who as adolescents were not approved for treatment.

Four of the appraised studies identified and variously described core and non-core groups of transsexuals, with core group transsexuals recording better outcomes than non-core groups. The retrospective cohort study by Landen et al. (1998) showed that pre-operative poor family support and non-core or secondary transsexualism were predictors of post-operative regret. Another follow-up study by Blandchard et al. (1989) found a high post-operative regret in biological males with heterosexual orientation. The study by Beatrice (1985) similarly found lower scores (higher degrees of mental instability) in the personality inventory of biological male heterosexuals and transvestites (non-core transsexuals) compared to post-operative transsexuals. A core group of post-operative M to F transsexuals, described as having symptomatology with stable ego, intact reality testing and poor genital interest, were shown to have greater satisfaction in quality of life indicators when compared with the non-core group (Sorensen, 1981).

A narrative review of published literature by Cohen-Kettenis and Gooren (1999) identified factors most likely to lead to post-operative regret being shortcomings in diagnosis, adequate real life experience and the quality of the surgery. Some of these conclusions concur with this review, specifically in diagnosis where those M to F who are secondary transsexual (transvestite or effeminate homosexual) have greater post-operative regret.

The methodological limitations of the appraised studies in this review included:

- weak study designs with mostly quasi-experimental studies or reviews of such literature
 - selection bias in subject recruitment methods and selection criteria and poor descriptions of these
 - outcome assessment tools were not often validated, inappropriate and data was not collected prospectively
 - low study power with small sample sizes, overlapping samples and high losses to follow-up; considerable variation (1-21 years) in the length of follow-up post-operatively
-

- rigorous and extensive diagnostic processes but high degree of heterogeneity in diagnostic methods; diagnostic criteria for subject selection often not well described
- no blinding of investigators to outcome assessment
- inadequate statistical methods and reporting of outcomes.

These limitations should be carefully kept in mind when interpreting the results of the studies appraised in this Tech Brief report.

CONCLUSIONS

There is insufficient evidence to prove the efficacy of gender reassignment surgery for specific subgroups of persons selected for such intervention. The subgroups of transsexual people who will most likely benefit from sex reassignment surgery are not clearly identifiable from the evidence reviewed. The evidence is based on a small number of studies with weak study designs and significant methodological limitations; the one systematic review (grade III-3) includes mostly poorer quality studies.

The appraised studies may indicate that early, rather than delayed sex reassignment surgery, is of greater benefit to transsexual people who have gone through rigorous assessment procedures and have been accepted for surgery. Several appraised studies identify characteristics of groups defined as core and non-core transsexual people but these are heterogeneous and anecdotal, most often being described as a diagnosis of primary or secondary transsexualism.

Sex reassignment surgery may be of benefit to some carefully assessed and selected transsexual people. Recognised diagnostic and eligibility criteria and care standards for surgery applicants from the Harry Benjamin Gender Dysphoria Association are increasingly being used in routine clinical practice. More research to improve the evidence base is needed to better ascertain the subgroups of transsexual people most likely to benefit from sex reassignment surgery.

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Note: see Appendices 3 and 4 for included appraised studies and excluded retrieved studies.

Appendix 1

LEVELS OF EVIDENCE

Level I	Evidence obtained from a systematic review (or meta-analysis) of relevant randomised controlled trials.
Level II	Evidence obtained from at least one randomised controlled trial.
Level III. 1	Evidence obtained from pseudorandomised controlled trials (alternate allocation or some other method).
2	Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case control studies or interrupted time series with a control group).
3	Evidence obtained from comparative studies with historical control, two or more single-arm studies or interrupted time series without a parallel control group.
Level IV	Evidence obtained from case series, either post-test or pretest/post-test.

Appendix 2

SEARCH STRATEGIES

Medline

1. gender reassignment.mp. (11)
2. transsexualism.mp. (208)
3. gender dysphoria.mp. (13)
4. (transsexual\$ or transgender\$).mp. (228)
5. (Trans-sexual\$ or trans-gender\$).mp. (4)
6. gender identity disorder.mp. (23)
7. sex reassignment.mp. (33)
8. sex change.mp. (30)
9. exp transsexualism/ (204)
10. or/1-9 (272)
11. letter.pt. (76595)
12. animal/ (389630)
13. 11 or 12 (461291)
14. 10 not 13 (117)
15. from 14 keep (selected references)

Psychinfo

1. gender reassignment.mp. (35)
2. transsexualism.mp. (934)
3. gender dysphoria.mp. (116)
4. (transsexual\$ or transgender\$).mp. (1119)
5. (Trans-sexual\$ or trans-gender\$).mp. (13)
6. gender identity disorder.mp. (239)
7. sex reassignment.mp. (197)
8. sex change.mp. (285)
9. exp sex change/ (137)
10. exp transsexualism/ (813)
11. or/1-10 (1420)
12. limit 11 to "0810 case study" (2)
13. limit 11 to 1200 letter (4)
14. 12 or 13 (6)
15. 11 not 14 (156)
16. limit 15 to english (153)
17. from 16 keep (selected references)(53)

Embase

1. gender reassignment.mp. (44)
 2. transsexualism.mp. (598)
 3. gender dysphoria.mp. (57)
 4. (transsexual\$ or transgender\$).mp. (695)
 5. (Trans-sexual\$ or trans-gender\$).mp. (15)
 6. gender identity disorder.mp. (71)
 7. sex reassignment.mp. (108)
 8. sex change.mp. (70)
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9. transsexualism/ (589)
10. or/1-9 (840)
11. limit 10 to english (691)
12. letter.pt. (214290)
13. 11 not 12 (648)
14. animal/ (6739)
15. animal experiment/ (547111)
16. 14 or 15 (550732)
17. 13 not 16 (632)
18. from 17 keep (selected references) (3)

Current Contents

1. gender reassignment.mp. (41)
2. transsexualism.mp. (169)
3. gender dysphoria.mp. (45)
4. (transsexual\$ or transgender\$).mp. (610)
5. (Trans-sexual\$ or trans-gender\$).mp. (13)
6. gender identity disorder.mp. (84)
7. sex reassignment.mp. (89)
8. sex change.mp. (214)
9. or/1-8 (923)
10. limit 9 to english (850)
11. letter or book review.pt. (694489)
12. 10 not 11 (725)
13. from 12 keep (selected references)

Other sources

Other sources where formal index terms were unavailable were searched using combinations of the keywords used in the strategies above.

Appendix 3

INCLUDED, CRITICALLY APPRAISED STUDIES

Barrett, J. (1998). Psychological and social function before and after phalloplasty. *International Journal of Transgenderism*, 2, Not paginated.

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Sorensen, T. (1981). A follow-up study of operated transsexual males. *Acta Psychiatrica Scandinavica*, 63, 486-503.

Tsoi, W. F. (1993). Follow-up study of transsexuals after sex-reassignment surgery. *Singapore Medical Journal*, 34, 515-517.

Appendix 4

EXCLUDED, RETRIEVED STUDIES

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- Daskalos, C. T. (1998). Changes in the sexual orientation of six heterosexual male-to-female transsexuals. *Archives of Sexual Behavior*, 27, 605-614.
- Di Ceglie, D., Bradley, S., Brain, C., Coates, S., Cohen-Kettenis, P., Green, R., Hul, P. et al. (1998). Gender identity disorders in children and adolescents: guidance for management. Royal College of Psychiatrists Council Report CR63. *International Journal of Transgenderism*, 2, Not paginated.
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